EFFICACY REVIEW

Product(s): BL-2003 Mole Bait

Date: May 18, 2004

EPA Reg No(s): 12455-RNR

DP Bar code(s): D298944

Chemical Code: Bromethalin 112802

Formulation(s): Bromethalin gel worm

Purpose for Review: The study listed below is an additional study in support of the BL-2003 Mole Bait and the purpose for this review is to determine if the Bromethalin gel worm is efficacious against the Eastern mole (*Scalopus aquaticus*) and the field data collected are acceptable for registration of the above named product.

MRID No(s): 46161201 Jeans, S. N. December 19, 2003. Efficacy of Bromethalin Mole Bait on Established Eastern Mole Populations. Bell Laboratories, Inc. Unpublished Report. Experiment #BEL/0703/BE515. 121pp.

Good Laboratory Practices: Yes

Branch Chief: Meredith Laws

Team Leader: John Hebert, Product Manager 07

IRB Reviewer: Geraldine R. McCann, Biologist

BACKGROUND: Bell Laboratories, Inc has applied for a new product registration for their **BL-2003 Mole Bait** (12455-RNR) formulated with the active ingredient Bromethalin. A previous review for this product dated March 19, 2004, found they held a captive population of moles and collected information about moles, their body weights, and their habits from July 23, 2002, until July 23, 2003. It was determined that using a diet solely comprised of nightcrawlers fed in excess of daily requirements, exceeds the daily requirements for nutrition and hydration substantiated by the body weight data collected on the captive population. The efficacy data guideline used to screen the bait for effectiveness for these product is OPP Pesticide Guideline Subdivision G 96-8 Mole Toxicants.

REVIEW OF DATA:

46161201 Jeans, S. N. December 19, 2003. Efficacy of Bromethalin Mole Bait on Established Eastern Mole Populations. Bell Laboratories, Inc. Unpublished Report. Experiment #BEL/0703/BE515. 121pp.

DISCUSSION: This field test is comprised of one test and one control site. They are within relative distance of each other, about 0.16 km (0.10 mile). The sites were measured as 0.40 hectares (0.99 acres) and 0.36 hectares (0.89 acres) test and control, respectfully. Other parameters measured daily during the testing were soil temperature, soil moisture, ambient environmental temperature, humidity, and precipitation. Both sites were measured, mapped, and monitored according to Bell Laboratories Test Method BIO515.1. The averages for both sites can be found on page 23 of 121.

The composition and formulation of the test bait is unique. It is in the form identified as Bromethalin Mole Bait with the active ingredient bromethalin and appears like a yellow rubber-like solid worm. Batch number L2113 (0.0221 % bromethalin) was used on the treated site. During storage of the bait (between manufacture and use), under ambient conditions in polyethylene bags, the bait analysis revealed loss of product stability. The bromethalin content dropped to 0.0193 %. Product stability in vacuum-sealed polypropylene bags is being explored in study BEL/0703/C324 Storage Stability and Corrosion Characteristics of Bromethalin Mole Bait. No dates associated with the study were mentioned.

A prod stick [2.5 cm (0.98 inches) diameter] was used to make the holes in the tunnel roof of the mole burrows to check for activity and to place the bromethalin worm. All the "sealed" holes were determined to be active. By study day 7, the test site had 24 initial active assessment holes with 15 that satisfied a ≥50% activity level and the control site had 17 of 23 active burrow systems that satisfied the ≥50% activity level. The individual 5 g bromethalin bait worms were placed in the burrow systems on Day 8 with a prod stick that was 1.3 cm (0.51 inches) in diameter. The burrow was sealed up to cover up any disturbance and entry of light. "Any targeted run system with measurable length of less than one meter was baited with two 5 gram gel worms at each end." The rate of application was 1 gel worm per meter of the burrow.

A Mole Contact Ratio (MCR) study was incorporated with the baiting study. This index was used to establish the potential mole exposure to the test material. The test site MCR (60 %) indicated the mole population had potential test material exposure in 60 % if the runs deemed active in the initial run selection phase. And the control site demonstrated a 94.1% MCR indicated that the same methodology could be used to predict mole movement with 94.1 % success. Details are discussed on pages 19 to 21 of 121.

The test areas were 2 residential southern Wisconsin homesites. The test and control sites exhibited similar agricultural practices. The soil samples from the two sites are relatively comparable:

Test Site	% Sand	% Silt	% Clay	pH	% Carbon	Texture
Treated	84	3	13	6.1	0.43	Loamy Sand
Control	80	7	13	7.2	0.73	Sandy Loam

The condition to warrant a second baiting session is outlined in the Bell Laboratories, Inc Test Method BIO515.1 (07/03/03): *If the reduction is less than 70%, a second baiting and corresponding follow-up period are conducted. The test and control sites are maintained for a period not to exceed 27 test days.* The Bromethalin Mole Bait was applied in a single application resulting in an 80% reduction in the Total Assessment Ratio within a seven day follow-up period and the control area experienced a 29.4% reduction in the Total Assessment Ratio.

Efficacy Comments

Guideline 96-8 (e)(1) states: *Submit the results of three acceptable field efficacy studies for each formulation, method of application, major region, and species claimed or implied to be controlled.* It is my opinion that the two studies associated with this product and the laboratory study are sufficient.

Guideline 96-8 (e)(v) states: *Verification of the target species. Because the method of censussing is an indirect one, some live trapping before censussing should be done to verify the species of mole and to record the species of mole captured.* No mention is made that the species of mole was trapped to check specifically for eastern moles. Star-nosed moles are also in the same areas in Wisconsin. Positive identification of the species of moles being treated is important because of the species specified on the label for the product. In future field studies, capturing the species of mole in the area where the testing is to occur is recommended.

Using the indirect method of censussing and no other means to determine if the moles are still in the area and inactive, or if they have moved off the treated area or died as a result of ingestion of the test material is impossible to determine. Even with all the valuable information gathered by the Bell Laboratories, the results of this study are not completely definitive; however, no further information is required at this time.

Conclusion(s) The Bell Laboratory test Experiment #BEL/0703/BE515 is acceptable and the efficacy data submitted to support the claims made for this product are acceptable per the comments made above.